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| 10/579,113 | 04/06/2007 | Richard Joseph Fagan | C&R-116 | 1499 |

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| EXAMINER | |
|---|---|
| SHAFER, SHULAMITH H | |

| ART UNIT | PAPER NUMBER |
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| 1647 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/579,113 | FAGAN ET AL. | |
| | Examiner | Art Unit | |
| | SHULAMITH H. SHAFER | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *42-49* is/are pending in the application.

4a) Of the above claim(s) *43 and 45-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,44 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

### *Status of Application, Amendments, And/Or Claims:*

Applicants' response of 30 June 2009 is acknowledged and made of record. Claims 30-41 have been canceled. New claims 42-49 are presented and made of record.

### *Restriction Requirement:*

Applicants' election, without traverse, of Group IV, claims 31-34 and 35-37 of claims as presented 11 May 2006, drawn to a method of treatment comprising administration of a pharmaceutical composition comprising a polypeptide, in the reply filed on 30 June 2009, is acknowledged. In response to requirement for species election, Applicants elect SEQ ID NO:22. The elected group corresponds to newly submitted claims 42-49.

Claims 42-49 are pending in the instant application. Claims 43, and 45-48 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 42, 44 and 49 are under consideration.

### *Priority:*

Acknowledgment is made of applicants' claim for foreign priority based on an application filed in United Kingdom on 12 November 2003. Receipt is acknowledged of GB 0326393 submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Priority is therefore granted to 12 November 2003.

### *Information Disclosure Statement:*

The Information Disclosure statements (IDS) submitted on the 6 February 2008 has been considered. The signed copy is attached.

The listing of references in the specification, for example paragraphs 0010, 0014, 0032, 0061 and 0064 of PGPUB 20080025951, the PGPUB of the instant application, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

## Objections

***Title:***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are drawn to a method of treatment comprising administration of a cytokine antagonist. It is suggested that the title be amended to reflect the claimed invention, for example, "A method of treatment comprising administration of a cytokine antagonist molecule".

***Sequence Rules:***

The specification is not in compliance with the requirements of 37 CFR 1.821 through 1.825 of the Sequence Rules and Regulations. Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing” in accordance with paragraph (c) of this section, reference must be made to the sequences by use of the sequence identifier, preceded by “SEQ ID NO:” in the text of the description or claims, even if the sequence is also embedded in the text or claims of the patent application.

37 CFR 1.821(a) presents a definition for nucleotide and/or amino acid sequences. This definition sets forth limits in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is

required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amno acids or an unbranched sequence of ten or more nucleotides. Please see MPEP 2422.01

Figures 1A and B disclose sequences. However, these sequences are not identified by sequence identifiers.

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.82(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03). **Compliance with the sequence rules is required**.

**Applicant must submit a response to this Office Action and compliance with the sequence rules within the statutory period set for response to this Office Action**

***Drawings:***

The drawings are objected to because Figures 1A and 1B disclose sequences without identifying said sequences by SEQ ID NOs (see discussion above).

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification:***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see paragraph 0270). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claims:***

Claim 42 is objected to because of the following informalities: there is a typographical error in the claim. The claim should be amended to insert an "and" in line 2 of the claim in between "carrier" and "a" so the claim reads "a pharmaceutically acceptable carrier *and* a polypeptide…".

**Rejections**

***Double Patenting Rejections:***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42, 44 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 33 of SSN 11/913,620. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

This is a provisional double patenting rejection since the conflicting claims have not, in fact, been patented.

Claims 42, 44 and 49 of the instant application are drawn to a method of treating a disease comprising administration of a composition comprising a pharmaceutically acceptable carrier and a polypeptide of SEQ ID NO:22. Claim 33 of co-pending application SSN 11/913,620 recites a method of treating a disease comprising administration of a composition comprising an INSPO52 polypeptide comprising or consisting of SEQ ID NO:22 (which is identical to SEQ ID NO:22 of the instant application). Among the diseases to be treated by the methods disclosed in SSN 11/913,620 is infectious disease. One of ordinary skill would interpret "infectious disease" as encompassing "a viral liver disease", as recited in claim 42 of the instant invention.

Thus, claim 33 of co-pending SSN 11/913,620 substantially overlaps the limitations recited in claims 42, 44 and 49 of the instant application.

***35 U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 44 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a disease wherein the disease is an acute liver disease or a skin disease wherein the disease is an inflammatory skin disease, does not reasonably provide enablement for a method of treating *any unspecified* auto-immune disease, a viral liver disease, *any unspecified* skin disease or *any unspecified* inflammatory disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to a method of treating a disease comprising administration of a composition comprising a pharmaceutically acceptable carrier and a polypeptide comprising (claim 43) or consisting of (claim 49) SEQ ID NO:22 to an individual having the disease wherein the disease is an auto-immune disease, viral liver disease, acute liver disease, skin disease, and inflammatory disease. Thus, the claims are broadly drawn to a method of treating **any** auto-immune, skin or inflammatory disease and a large genus of liver diseases (acute and viral).

The scope of the patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons.

The specification discloses that SEQ ID NO:22, the elected species is the extracellular domain of INSP052 (also referred to by applicants as INSP052EC) [paragraph 0033]. This polypeptide downregulates TNF-alpha, IL-4 and IL-2 secretion *in vitro* in a Concanavalin A (ConA) stimulated human peripheral blood mononuclear cells (hPBMC) assay and in a similar assay using CD4+ T cells. In addition, delivery of INSP052EC cDNA in an *in vivo* model of fulminant hepatitis was found to decrease TNF-alpha and m-IL-6 levels in serum and reduced transaminases measured in serum. This effect was confirmed by subcutaneous INSP052EC protein injections [paragraph 0033]. In a model of LPS-induced cytokine release in mice, the polypeptide down-regulated the LPS-induced TNF alpha or IL-6 release [paragraph 0035]. Administration of the polypeptide of SEQ ID NO:22 to mice with hapten-induced contact hypersensitivity (CHS), a murine model of inflammatory skin disease, reduces ear swelling in a significant and dose-dependent manner, suggesting a decrease in leukocyte infiltration and of the consequent inflammation [paragraph 0036]. Based on these results, applicants envision that the polypeptide of the instant invention are inhibitory of pro-inflammatory cytokines, functioning in particular as an antagonist of cytokine secretion and/or expression, may have a therapeutic role in diseases directly or indirectly related to both innate and adaptive immune responses and may be useful in treating auto-immune, viral or acute liver diseases as well as alcoholic liver failures. The polypeptide (SEQ ID NO:22) is likely also to be effective in treating other inflammatory diseases [paragraph 0037]. The polypeptide may therefore be used to treat inflammatory diseases, auto-immune diseases, skin disease, liver disease and liver failure [paragraph 0094]. However, the specification fails to provide sufficient guidance as to how to utilize the polypeptide of the instant invention to treat the broad range of diseases encompassed by the claims of the instant invention.

In the instant case, the nature of the invention is complex, involving the effects of proteins, specifically the protein of SEQ ID NO:22, on a multitude of complex pathological conditions involving diverse etiologies, progressions and outcomes. It is noted that the courts have long settled that such is considered complex. See Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), wherein it was determined that a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amqen Inc. v. Chuqai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

The teachings in the art fail to overcome the lack of guidance in the specification. Feldmann (2008. J Clin Invest 118:3533-3536) cautions that clinical trials with anti-cytokine therapy, specifically TNF-α blockade, have had variable success and that there are differences between results in animal models, where many anti-cytokine therapies are very effective and the human disease, treatment of which is proving more challenging (page 3533, 2nd column, 3rd paragraph). Steinman (2008. J. Clin Invest 118:3557-3563) teaches that many cytokines have a major impact in the pathogenesis of multiple sclerosis (MS), a neurodegenerative autoimmune disease; however, blockade of TNF-α is associated with worsening of MS (page 3559, 2nd column, last paragraph, bridging page 3560, 1st column, 1st paragraph). Barnes (2008. J. Clin Invest 118:3546-3556) teaches that the most common inflammatory diseases of the airways are asthma and chronic obstructive pulmonary disease (COPD); cytokines play a key role in orchestrating the chronic inflammation and structural changes of the respiratory tract in both of these diseases (abstract). However, the reference teaches that "Although there have been several attempts to inhibit specific cytokines in asthma and COPD with blocking antibodies, the results have so far been disappointing ..." (page 3553, 2nd column, 2nd paragraph). Yamagata et al (2006. European J of Pharm 533:289-301) teach that "inhibition of IL-4… showed promising early results for asthma,

however, this was not confirmed in subsequent clinical trials. Antibodies that block IL-5 effectively inhibit peripheral blood and airway eosinophilia, but it does not also seem to be effective in symptomatic asthma." (page 297, 1st column, 2nd paragraph). Dinarello (2000. Chest. 503-508) teaches that blocking TNF has been highly successful in treating patients with rheumatoid arthritis, inflammatory bowel disease or graft-vs-host disease but distinctly has not been successful in treating humans with sepsis (abstract). Anti-TNF-α therapy has been shown to be effective in the treatment of one type of inflammatory bowel disease (IBD), Crohn's Disease, but was ineffective in treatment of another type of IBD, Ulcerative colitis (Andreakos. 2003. Expert Opin Biol Ther. 3:435-447, page 437, 2nd column, 1st paragraph). Thus, the art teaches that blocking inflammatory cytokines may be effective therapies in some inflammatory diseases but are ineffective in the treatment of others. Therefore, one of ordinary skill would be unable to predict that the methods of the instant invention would be effective in treatment of all auto-immune or inflammatory diseases.

The art teaches that therapies comprising antagonism of TNF-α should be used cautiously in the treatment of liver disease. Tilg (2001. Can J. Gastroenterol. 15:661-668) teaches several cytokines mediate hepatic inflammation, apotosis and necrosis of liver cells, cholestasis and fibrosis; the same mediators also mediate the regereration of liver tissue after injury. The reference teaches "antagonism of TNF-α and other injury-related cytokines in liver diseases merits evaluation as a treatment of these diseases. However, because the same cytokines are also necessary for the regeneration of the tissue after the liver has been injured, inhibition of these mediators might impair hepatic recovery" (abstract). Nathan et al (2006. J Gastroent. and Hepat. 21:1366-1371) teaches that anti-TNF-α therapy is associated with activation of hepatitis B virus infection with potentially fatal outcome (abstract), thus teaching away from utilization of the methods of the instant invention to treat a viral liver disease.

One of ordinary skill is aware that there are many different skin diseases, some of which are not related to inflammatory disorders. Trefzer et al (2003. Expert Opin Biol Ther. 3:733-743) teach the efficacy of drugs which target TNF-α in the treatment of psoriasis and other skin diseases (page 738, 2nd column, paragraph 4.1.7, page 739, 1st

column, section 5) but cautions that such treatments are associated with cases of tuberculosis and other serious infections, including sepsis. Additionally, the review teaches that the biological effect of one cytokine is often modified or augmented by another cytokine and that interfering with the effect of a single or several cytokines, might not represent the best approach (page 739, 2nd column, 1st paragraph).

Thus, the preponderance of the art teaches that results obtained in animal models do not necessarily translate as effective treatments in humans, therapies which may be effective in treatment of one inflammatory or autoimmune disease may not be effective in treating a different inflammatory or autoimmune disease and urges caution in using anti-cytokine therapies which may result in unpredictable side effects.

Therefore, based on the discussions above concerning the art's recognition that results obtained in animal models may not be representative of the efficacy of treatments in humans and the recognition that therapies blocking the activity of inflammatory cytokines may not be effective in treating a broad range of autoimmune, inflammatory, skin or liver diseases, the specification fails to teach the skilled artisan how to use the claimed methods without resorting to undue experimentation.

Due to the large quantity of experimentation necessary to determine which of the numerous autoimmune, inflammatory, skin or liver diseases may be treated with the methods of the instant invention, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, the state of the prior art establishing that results obtained in animal models may not be representative of the efficacy of treatments in humans, and the breadth of the claims which fail to recite specific autoimmune, inflammatory, skin or liver diseases, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Baughn et al. (US 20040043424, filed 16 May 2003).

The claims are drawn to a method of treating a disease comprising administration of a composition comprising a pharmaceutically acceptable carrier and a polypeptide comprising SEQ ID NO:22. The diseases to be treated may be autoimmune disease, a viral or acute liver disease, a skin disease or an inflammatory disease.

Baughn et al. teaches a method of treatment comprising administration of a polypeptide of the immunoglobulin superfamily of peptides, IGSFP-4 (SEQ ID NO:4). SEQ ID NO:4 comprises a polypeptide which is 100% identical to SEQ ID NO:22 of the instant invention (See results in SCORE and the alignment below).

```
SEQ ID NO 4
  Query Match             100.0%;  Score 1045;  DB 4;  Length 298;
  Best Local Similarity   100.0%;  Pred. No. 2.1e-87;
  Matches  207;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 VNITSPVRLIHGTVGKSALLSVQYSSTSSDRPVVKWQLKRDKPVTVVQSIGTEVIGTLRP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         34 VNITSPVRLIHGTVGKSALLSVQYSSTSSDRPVVKWQLKRDKPVTVVQSIGTEVIGTLRP 93

Qy         61 DYRDRIRLFENGSLLLSDLQLADEGTYEVEISITDDTFTGEKTINLTVDVPISRPQVLVA 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         94 DYRDRIRLFENGSLLLSDLQLADEGTYEVEISITDDTFTGEKTINLTVDVPISRPQVLVA 153

Qy        121 STTVLELSEAFTLNCSHENGTKPSYTWLKDGKPLLNDSRMLLSPDQKVLTITRVLMEDDD 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        154 STTVLELSEAFTLNCSHENGTKPSYTWLKDGKPLLNDSRMLLSPDQKVLTITRVLMEDDD 213
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Qy        181 LYSCMVENPISQGRSLPVKITVYRRSS 207
              ||||||||||||||||||||||||||||
Db        214 LYSCMVENPISQGRSLPVKITVYRRSS 240
```

The administered polypeptide may be part of a composition comprising a pharmaceutical carrier [paragraph 0194]. The composition is administered to treat disorders of the immune system. Among diseases to be treated are allergies, contact dermatitis, Crohn's disease, atopic dermatitis, psoriasis and hepatitis [paragraph 0193], therefore teaching treatment of auto-immune, inflammatory, skin and liver diseases. Thus, the teachings of Baughn et al anticipate all the limitations of claims 42 and 43.

Claim 49 is free of the prior art.

***Conclusion:***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer/
Examiner, Art Unit 1647